

3. The system includes the use of the disinfecting solution with the AOSEPT® Disposable Cup & Disc.

4. The AOSEPT® Disinfecting Solution is intended to be used with the AOSEPT® Disposable Cup & Disc.

5. The AOSEPT® Disposable Cup & Disc is a specially-designed apparatus to hold the contact lenses and the AOSEPT® Disinfecting Solution during the disinfecting process, and which provides catalytic decomposition of hydrogen peroxide and permits gas generated by the AOSEPT® Disinfecting Solution to vent without the loss of liquid.

6. The solution must be used with the AOSEPT® Disposable Cup & Disc to ensure the disinfecting solution is neutralized after the disinfection process so that the contact lens can safely be put back in the eye.

7. The AOSEPT® Disinfecting Solution cannot safely be used with a normal flat contact lens case. Failure to use the AOSEPT® Disposable Cup & Disc can result in residual, un-neutralized hydrogen peroxide being placed in the eye along with the contact lens, which could be quite painful.

8. CIBA Vision marks the primary packaging for the AOSEPT® Disinfecting Solution (*i.e.*, the bottle containing the solution) with U.S. Patent No. 4,889,689 (the “ ’689 patent”).

9. The ’689 patent is a method patent generally directed towards a method of disinfecting contact lenses.

10. In the application that led to the ’689 patent, the U.S. Patent & Trademark Office cancelled some claims concerning the underlying solution, but several other claims remained covering the method of disinfecting a soft contact lens with a stabilized aqueous hydrogen peroxide solution, and compositions for use in such method.

11. The intended use of the AOSEPT® Disinfecting Solution with the AOSEPT® Disposable Cup & Disc to disinfect a soft contact lens would fall within the scope of claim 1 of the '689 patent.

12. The outer or secondary packaging for the AOSEPT® Disinfecting Solution is marked with the '689 patent and three additional patents: U.S. Patent Nos. 5,558,846 (the “ '846 patent”); 5,609,264 (the “ '264 patent”); and 5,609,837 (the “ '837 patent”). The marking also includes the statement “and other patents pending.”

13. The '846, '264, and '837 patents are directed towards various aspects of soft contact lens cases and cover the AOSEPT® Disposable Cup & Disc.

14. The artwork used on the outer packaging for AOSEPT® Disinfecting Solution, as well as the artwork used on the labels for the bottles themselves, was subjected to a copy approval review process conducted by a multidisciplinary committee within CIBA Vision, which included representatives from Marketing, Professional Services, Regulatory Affairs, Legal, and Package Engineering.

15. The multidisciplinary committee approved the pertinent artwork for the AOSEPT® packaging and bottles at various points in time, including in 2004 and again in 2006.

16. Because the AOSEPT® Disinfecting Solution is a medical device regulated by the U.S. Food & Drug Administration (“FDA”), statements made in the packaging, labeling, and advertising for the product must comply with FDA regulations.

17. During the relevant period, CIBA Vision’s then-Chief Patent Counsel, Robert G. Gorman, Esquire, was responsible for review of patent markings as part of CIBA Vision’s internal copy approval process.

18. Gorman testified that he approved the patent markings for AOSEPT® Disinfecting

Solution when they first appeared in 2004, and again in 2006.

19. Gorman explained his procedure for conducting reviews of patent markings in the copy approval process, which included downloading the patents, examining the claims, and comparing them to the product.

20. Gorman further testified that he approved the marking of both the primary and outer packaging with the '689 patent based on his understanding of the federal policy of encouraging patent holders to inform the public of the patents that cover a product and that with a method patent, where there is something tangible to mark, the product should be marked.

21. Gorman testified that the three patents which cover the AOSEPT® Disposable Cup & Disc were marked along with the '689 patent on the outer or secondary packaging because the instructions for the use of the disinfecting solution provide that the disinfecting solution must be used with the AOSEPT® Disposable Cup & Disc for safety reasons, keeping in mind the FDA regulations of these products.

22. Gorman also testified he believed that when the markings were approved, there were other patents pending which covered AOSEPT® Disinfecting Solution, based on earlier work he had done in prosecuting patent applications on various aspects of peroxide systems.

23. Gorman testified that he believed the markings he approved in 2004 and 2006 for AOSEPT® Disinfecting Solution were proper, and that he did not have any reason to believe the markings were false.

II. CONCLUSIONS OF LAW

Federal patent law prohibits the intentional false marking of articles of commerce for purposes of deceiving the public into believing that an article has patent protection when it does not. Section 292 provides:

Whoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article, the word “patent” or any word or number importing that the same is patented for the purpose of deceiving the public . . . [s]hall be fined not more than \$500 for every such offense.

35 U.S.C. § 292(a) (2006).

“The two elements of a § 292 false marking claim are (1) marking an unpatented article and (2) intent to deceive the public.” Forest Group, Inc. v. Bon Tool Co., 590 F.3d 1295, 1300 (Fed. Cir. 2009) (citing Clontech Labs, Inc. v. Invitrogen Corp., 406 F.3d 1347, 1352 (Fed. Cir. 2005)). An “unpatented article” is an article that “is not covered by at least one claim of each patent with which the article is marked.” Clontech Labs., 406 F.3d at 1352. The Federal Circuit has recognized that in determining whether an article is unpatented under this statute, “it must be first determined whether the claims of a patent cover the article in question.” Id. “To make that determination, the claim in question must be interpreted to ascertain its correct scope, and then it must be ascertained if the claim reads on the article in question.” Id.

As to the second prong of a false marking claim, “[i]ntent to deceive is a state of mind arising when a party acts with sufficient knowledge that what it is saying is not so and consequently that the recipient of its saying will be misled into thinking that the statement is true.” Forest Group, Inc., 590 F.3d at 1300 (citing Seven Cases v. United States, 239 U.S. 510, 517-18 (1916)); see also Clontech Labs., 406 F.3d at 1352. As the Federal Circuit stated in Clontech:

Intent to deceive, while subjective in nature, is established in law by objective criteria. Thus, “objective standards” control and “the *fact* of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent.” Thus, under such circumstances, the mere assertion by a party that it did not intend to deceive will not suffice to escape statutory liability. Such an assertion, standing alone, is worthless as proof of no intent to deceive where there is knowledge of falsehood. But in order to establish knowledge of falsity the plaintiff must show by a preponderance of the evidence that the party accused of false marking did not have a reasonable belief that

the articles were properly marked (i.e., covered by a patent). Absent such proof of lack of reasonable belief, no liability under the statute ensues.

406 F.3d at 1352-53 (citations omitted). ¹

Here, as discussed below, the Court finds that Plaintiff has failed to meet his burden of proving either element of a § 292 violation. First, it is unclear that items are “unpatented articles” within the meaning of the statute. In addition, Plaintiff has failed to prove by a preponderance of the evidence that CIBA Vision had an intent to deceive the public. On the contrary, the evidence demonstrates CIBA Vision had a good faith belief that it properly marked the products in question.

A. “Unpatented Article”

1. '689 patent

Both the primary packaging and outer packaging of AOSEPT® Disinfecting Solution are marked with the '689 patent, which pertains to a method of disinfecting soft contact lenses. The '689 patent covers the use of the AOSEPT® Disinfecting Solution with the AOSEPT® Disposable Cup & Disc to disinfect soft contact lenses, which is the intended use of the product. Because the claims of the '689 patent cover the use of the AOSEPT® Disinfecting Solution, the Court finds that AOSEPT® Disinfecting Solution is not an “unpatented article” as that term is used in § 292. Clontech, 406 F.3d at 1352 (“[T]o determine if an article is ‘unpatented’ for purposes of section 292, it must first be determined whether the claims of a patent cover the article in question.”).

To determine whether the claims of a method patent cover an article when the use of that article is covered by the claims, the Court turns to the federal marking statute, which requires patent holders to affix a notice of patent to a protected article in order to recover damages from an

¹ Under Clontech, “the combination of a false statement and knowledge that the statement was false creates a rebuttable presumption of intent to deceive the public, rather than irrebuttably proving such intent.” Pequignot v. Solo Cup Co., --- F.3d ---, 2010 WL 2346649, at *6 (Fed. Cir. June 10, 2010).

infringer. 35 U.S.C. § 287. “The purpose behind the marking statute is to encourage the patentee to give notice to the public of the patent.” Am. Med. Sys., Inc. v. Med. Eng’g Corp., 6 F.3d 1523, 1538 (Fed. Cir. 1993).

As the Supreme Court explained in Bonito Boats, Inc. v. Thunder Craft Boats, Inc., the notice requirement of § 287 is designed to provide “a ready means of discerning the status of the intellectual property *embodied* in an article.” 489 U.S. 141, 162 (1989) (emphasis added). The Supreme Court in Bonito Boats also embraced the Federal Circuit’s opinion in Devices for Medicine, Inc. v. Boehl that where a patentee has sold a product which “embodies” a patent without marking, the patentee “could hardly maintain entitlement to damages for its use by a purchaser uninformed that such use would violate [the] method patent.” 489 U.S. at 162 (citing Devices for Medicine, Inc. v. Boehl, 822 F.2d 1062, 1066 (Fed. Cir. 1987)). In Devices for Medicine, the claims at issue were method claims which covered the product. 822 F.2d at 1066. In short, the Supreme Court and the Federal Circuit have recognized that method claims can be intellectual property “embodied” in an article. Where there is a tangible product to mark, failure to mark the product with the patent containing the method claims could prevent recovery of damages for infringement of those claims.²

The Supreme Court’s holding in Quanta Computer, Inc. v. LG Electronics, Inc. that a product whose use is covered by a patent containing only method claims is a “patented item” for purposes

²Whether CIBA Vision was required to mark AOSEPT® Disinfecting Solution with the ’689 patent is a separate question, and one the Court need not reach. Whether the marking requirement applies to a product covered by a patent which contains only method claims where there is something tangible to mark is unsettled. In 2003, the Federal Circuit specifically reserved on this question. State Contracting & Eng’g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1073 (Fed. Cir. 2003). The Federal Circuit has held previously that the notice requirement of § 287 does not apply where the patent is directed to a process or method. Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1316 (Fed. Cir. 2009); Am. Med. Sys., 6 F.3d at 1538; Devices for Medicine, 822 F.2d at 1066. In American Medical Systems, the Federal Circuit explained, however, that “[t]he reason that the marking statute does not apply to method claims is that, ordinarily, where the patent claims are directed to only a method or process there is nothing to mark.” 6 F.3d at 1538.

of the doctrine of patent exhaustion is also instructive on this point. 128 S. Ct. 2109, 2119 (2009).

The Supreme Court opined:

It is true that a patented method may not be sold in the same way as an article or device, but methods nonetheless may be “embodied” in a product, the sale of which exhausts patent rights. Our precedents do not differentiate transactions involving embodiments of patent methods or processes from those involving patented apparatuses or materials. To the contrary, this Court has repeatedly held that method patents were exhausted by the sale of an item that embodied the method.

Id. at 2117. The Court believes Quanta Computer’s holding that an article whose use is covered by a method patent is a “patented item” for purposes of the patent exhaustion doctrine compels the conclusion that the same product is a “patented article” for purposes of § 292. An item cannot be a “patented item” for purposes of the patent exhaustion doctrine and an “unpatented article” for purposes of § 292. Thus, Quanta Computer supports the conclusion that AOSEPT® Disinfecting Solution is covered by the ’689 patent and that the AOSEPT® Disinfecting Solution is not an “unpatented article” for purposes of § 292. As a result, the Court finds neither the outer packaging nor the bottles of AOSEPT® Disinfecting Solution are “falsely” marked with the ’689 patent.³

2. The Cup Patents

The ’846, ’264, and ’837 patents are marked on the outer or secondary packaging in which the AOSEPT® Disinfecting Solution is sold. As stipulated by the parties, these three patents cover various aspects of the soft contact lens cases and cover the AOSEPT® Disposable Cup & Disc. These patents are not marked on the bottles of the solution themselves.

³ Following the bench trial in this case, the Federal Circuit rendered its opinion in Pequignot v. Solo Cup Company, which recognized that articles marked with expired patents are “unpatented” within the meaning of the false marking statute. --- F.3d ---, 2010 WL 2346649 at *4-6 (Fed. Cir. June 10, 2010). However, as the Federal Circuit recognized, marking an article with an expired patent alone does not decide the question of liability under the false marking statute as Plaintiff must show the marking was done “for the purpose of deceiving the public.” Id. at *5-6; 35 U.S.C. § 292. To the extent this decision is applicable here, the Court believes even if an article were “unpatented” within the meaning of § 292, Plaintiff has still failed to carry his burden of showing intent to deceive the public.

The Court finds it was not false to mark the outer packaging with these three patents. The packaging describes and depicts in pictures the entire AOSEPT® Cleaning and Disinfecting System, including both the AOSEPT® Disinfecting Solution and the AOSEPT® Disposable Cup & Disc. The packaging instructions state clearly that the AOSEPT® Disinfecting Solution must be used with the AOSEPT® Disposable Cup & Disc. As such, the Court finds it was proper to mark the outer packaging with the four patents which cover the system, including the three cup patents and the method patent covering the use of the solution.

3. The Patents Pending

The Court further finds that it was not false to include “and other patents pending” in the patent marking on the bottles and the outer packaging. Gorman, CIBA Vision’s former Chief Patent Counsel, credibly testified he believed there were other patent applications pending that were relevant to AOSEPT® Disinfecting Solution. Plaintiff adduced no evidence to contradict Gorman’s testimony. Accordingly, the Court finds Plaintiff has failed to carry his burden of proving that there were no other patents pending which covered this article.

In sum, the Court finds Plaintiff has failed to demonstrate that the bottles and outer packaging of the AOSEPT® Disinfecting Solution are falsely marked. Therefore, on this ground alone, the Court finds Plaintiff has not carried his burden of demonstrating that CIBA Vision violated § 292.

B. “For the Purpose of Deceiving the Public”

The Court further finds Plaintiff has failed to prove that CIBA Vision acted with the requisite intent to deceive the public. Plaintiff presented evidence during trial that in the application leading to the ’689 patent, the U.S. Patent & Trademark Office cancelled some claims concerning the underlying solution. However, several other claims remained covering the method of disinfecting

a soft contact lens with a stabilized aqueous hydrogen peroxide solution, and compositions for use in such method. On the remaining claims, the '689 patent was issued.

Gorman testified without contradiction that he approved the marking on both the primary and outer packaging with the '689 patent based on his understanding of the federal policy encouraging patent holders to inform the public of the patents that cover a product, and that where a method patent exists and there is something to mark, the product should be marked. As previously noted, the issue of whether the marking requirement applied to a product covered by a patent which contains only method claims where there is something tangible to mark is unsettled, but failure to mark the product with the patent containing the method claims could prevent recovery of damages for infringement of those claims. Supra n.2; see also Bonito Boats, Inc., 489 U.S. at 162; Devices for Medicine, Inc., 822 F.2d at 1066. As a result, the Court is not convinced, as previously stated, that there was a false statement here. However, even assuming, *arguendo*, that there was a false statement here, CIBA Vision has presented evidence of good faith reliance on the advice of counsel. The evidence demonstrates that CIBA Vision believed its products were properly marked in accordance with federal patent law based on the advice of its then-Chief Patent counsel.

In addition, the Court is persuaded by Gorman's uncontradicted testimony that he believed the three other patents, which cover the AOSEPT® Disposable Cup & Disc, were marked on the outer cover along with the '689 patent for safety reasons consistent with FDA regulations. The outer packaging contained instructions for the AOSEPT® Cleaning and Disinfecting System, including both the AOSEPT® Disinfecting Solution and the AOSEPT® Disposable Cup & Disc. The instructions made clear that the disinfecting solution must be used with the AOSEPT® Disposable Cup & Disc. Failure to follow the system could result in the disinfecting solution being placed directly in the eye, which could be painful. Further, Gorman's testimony that, based on earlier work

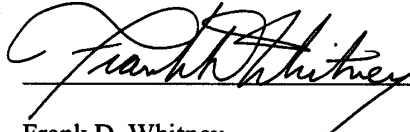
he did in prosecuting patent applications on various aspects of peroxide systems, he believed there were other patents pending concerning AOSEPT® Disinfecting Solution demonstrates CIBA Vision had a reasonable belief that the markings were proper. Based on this, the Court believes CIBA Vision had a good faith belief that it should mark its packaging as it did, and Plaintiff has failed to satisfy the high bar set for proving deceptive intent.

III. CONCLUSION

Plaintiff has failed to satisfy his burden in proving that CIBA Vision violated 35 U.S.C. § 292 with its patent marking of the AOSEPT® Disinfecting Solution. Accordingly, the Clerk is directed to enter judgment in favor of Defendant CIBA Vision in accordance with the above opinion, and subsequently close the case.

IT IS SO ORDERED.

Signed: July 21, 2010


Frank D. Whitney
United States District Judge

